

SECTION 11

JAN 17 2007

510(k) SUMMARY**[As Required by 21 CFR 807.92(c)]**

Information supporting claims of substantial equivalence, as defined under the Federal Food, drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

510(k) Summary Date prepared

November 6, 2006

510(k) Submitter

PETERS SURGICAL
Z.I. Les vignes
42 rue Benoît Frachon
Bobigny, FRANCE 93013

Registration Number: 3004060107
Owner/Operator Number: 9009304
Phone: 33-148-106262
Fax: 33-148-912299

Official Correspondent

Hinda BENKIRANE
Regulatory Affairs Manager
PETERS SURGICAL Bobigny, FRANCE, 93013
Phone: 33-148-106254

New Device Name

Trade name:	PREMIO®
Common/Usual name:	Polyvinylidene fluorure Synthetic Nonabsorbable Suture
Classification name:	Suture, Nonabsorbable, Synthetic, Polypropylene

New Device Classification

Class II in 21 CFR §878.5010 by the General and Plastic Surgery Devices Panel,
Nonabsorbable Polypropylene Surgical Suture (GAW).

Predicate Device Name

PRONOVATM, Nonabsorbable Surgical Suture (K001625).

Statement of intended use

PREMIO[®] sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular and vascular surgery, in ophthalmic surgery and in neurological surgery.

PREMIO[®] has the same intended use as the predicate device PRONOVATM.

New Device Description

PREMIO[®] is a synthetic non-absorbable surgical suture composed of a polyvinylidene fluoride monofilament blue dyed with Phthalocyanine Copper. The suture may be provided with or without pledget.

Summary of Technological Characteristics of New Device compared to Predicate Device

Our new device PREMIO[®] has similar technological characteristics as the predicate device PRONOVATM. Like currently marketed PRONOVATM suture, PREMIO[®] is a sterile monofilament synthetic non-absorbable surgical suture that conforms to the requirements of the United States Pharmacopoeia (USP) and the European Pharmacopoeia (EP) for non-absorbable surgical sutures. The raw material used for both medical devices is commonly used in surgical applications and has been proven to be biocompatible.

Performance data

Non-clinical laboratory testing was performed demonstrating that the device complied with the USP Monographs and with the EP Monographs for non-absorbable surgical sutures.

Conclusions

Based on the 510(k) summary (21 CFR 807) and the information provided herein, we conclude that our New Medical Device PREMIO[®] is substantially equivalent to the Predicate Device PRONOVATM under the Federal Food, Drug, and Cosmetic Act.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Peters Surgical
% Ms. Annie Lasserre
Z.I. Les vignes
42 Rue Benoît FRACHON
Bobigny, FRANCE 93013

JAN 17 2007

Re: K060465

Trade/Device Name: PREMIO®
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: II
Product Code: MXW
Dated: November 6, 2006
Received: November 24, 2006

Dear Ms. Lasserre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

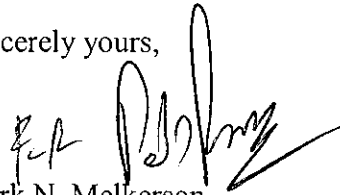
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Annie Lasserre

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 10

STATEMENT OF INDICATIONS FOR USE

510(k) Number K060465

Device Name PREMIO®

Indications for use

PREMIO® sutures are intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular and vascular surgery, in ophthalmic surgery and in neurological surgery.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K060465